Alabama Medicaid Agency

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Montgomery, Alabama 36103-5624

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Telecommunication for the Deaf: 1-800-253-0799
1-800-362-1504 (334) 293-5500

BOB RILEY
Governor

MIKE LEWIS
Acting Commissioner

August 25, 2003

Provider Notice 03-09

TO: Medicaid Physicians, Pharmacies, Optometrists, FQHC's, RHC's and Nursing Homes

RE: Pharmacy Prior Authorization Form

Effective September 3, 2003, the attached Prior Authorization Request Form should be utilized by the prescribing physician or the dispensing pharmacy in requesting pharmacy prior authorizations. This two-page form will replace the current PA forms. This change is being made at the request of our providers in an effort to simplify the PA process. It is still very important that all information be completed and that both pages of the form be submitted. Requests may be faxed, or mailed to:

Health Information Designs (HID)
Medicaid Pharmacy Administrative Services
P. O. Box 3210
Auburn, AL 36832-3210
Fax: 1-800-748-0116
Phone: 1-800-748-0130

A detailed instruction sheet for the completion of the request form is also being provided to you with this notice. Specific drug criteria information is available on the Medicaid web site at www.medicaid.state.al.us. Incomplete PA requests or those failing to meet Medicaid criteria will be denied. If the prescribing physician believes additional medical justification should be considered, the physician must document this on the form or submit a written letter of medical justification along with the prior authorization form. Staff physicians will review this information.

Policy questions concerning this provider notice should be directed to Louise F. Jones, Pharmacy Services Division at 334-242-5050. Questions regarding prior authorization procedures should be directed to the HID help desk at 1-800-748-0130.

Mike Lewis
Acting Commissioner

Distribution

Alabama Independent Drugstore Association	Alabama Pharmacy Coop	State of Alabama Medical Association
Alabama Pharmacy Association	Alabama Retail Association	Medical Association of the State of Alabama
Alabama Primary Healthcare Association	Alabama Nursing Home Association	Alabama Optometric Association

Medicaid Pharmacy
Prior Authorization Request Form

FAX: (800) 748-0116
Phone: (800) 748-0130

Fax or Mail to
Health Information Designs

P.O. Box 3210
Auburn, AL 36823-3210

PATIENT INFORMATION

Patient Name _____ Patient Medicaid # _____

Patient DOB _____ Patient phone # with area code _____

Nursing Home Resident ❒ Yes ❒ No

PRESCRIBER INFORMATION

Prescribing practitioner _____ License # _____

Address _____ Phone # with area code _____

City/State/Zip _____ Fax # with area code _____

I certify that this treatment is indicated and necessary and meets the guidelines for use as outlined by the Alabama Medicaid Agency. I will be supervising the patient's treatment. Supporting documentation is available in the patient record.

_____

Prescribing practitioner signature Date

DISPENSING PHARMACY INFORMATION

Dispensing pharmacy _____ Provider # _____

Phone # with area code _____ Fax # with area code _____

DRUG/CLINICAL INFORMATION

Required for all requests

Drug Requested _____ Strength _____

NDC # or J Code _____ Qty. requested per month _____ Number of refills _____

Diagnosis _____ ICD-9 Code*_____

Diagnosis _____ ICD-9 Code*_____

❒ Initial Request ❒ Renewal

Medical justification _____

_____

❒ **Additional medical justification attached.**

***See Instruction Sheet, Section 4**

DRUG SPECIFIC INFORMATION

❒ **NSAID** ❒ **Antihistamine** ❒ **H2 Antagonist** ❒ **PPI** ❒ **Antidepressants** ❒ **Narcotic Analgesics**
❒ **Platelet Aggregation Inhibitors**

❒ **Acute Therapy** ❒ **Maintenance Therapy**

List previous drug usage for drug class requested

Generic/Brand/OTC _____ Reason for d/c _____

Generic/Brand/OTC _____ Reason for d/c _____

If no previous drug usage, additional medical justification must be provided.

NOTE: See Instruction sheet for specific PA requirements on the Medicaid website at www.medicaid.state.al.us

❒ Sustained Release Oral Opioid Agonist

Proposed duration of therapy _____ Is medicine for PRN use? ❒ Yes ❒ No

Type of pain ❒ Acute ❒ Chronic Severity of pain: ❒ Mild ❒ Moderate ❒ Severe

Is there a history of substance abuse or addiction? ❒ Yes ❒ No

If yes, is treatment plan attached? ❒ Yes ❒ No

Indicate prior and/or current analgesic therapy and alternative management choices

Drug/therapy _____ Reason for d/c _____

Drug/therapy _____ Reason for d/c _____

❒ TNF Blocker ❒ Remicade^{R} ❒ Enbrel™ ❒ Kineret™ ❒ Humira™

If Rheumatoid Arthritis, is therapy approved by a board certified Rheumatologist? ❒ Yes ❒ No

Prior and/or current DMARD therapy? ❒ Yes ❒ No If yes, attach documentation.

If Crohn's disease, is therapy approved by a board certified Gastroenterologist? ❒ Yes ❒ No

If Remicade^{R} is requested for Rheumatoid Arthritis, will patient be on Methotrexate? ❒ Yes ❒ No

If no, contraindication to use _____

If Psoriatic Arthritis, is therapy approved by a board certified Dermatologist? ❒ Yes ❒ No

❒ Xenical

❒ If initial request Weight _____lbs. Height _____inches BMI _____kg/m^2

❒ If renewal request Previous weight _____lbs. Current weight _____lbs.

Documentation MD supervised exercise/diet regimen ≥ 6 mo.? ❒ Yes ❒ No Planned adjunctive therapy? ❒ Yes ❒ No

❒ Erectile Dysfunction Drugs

Gender ❒ Male ❒ Female Age: ❒ <18 years ❒ 18 years or older

Prior drugs or devices used within past 12 months

1. _____ Date _____ Reason for d/c _____

2. _____ Date _____ Reason for d/c _____

Active or recent history of sexually transmitted disease? ❒ Yes ❒ No

Etiology of dysfunction confirmed by H & P

❒ Spinal cord injury ❒ Diabetic neuropathy ❒ TURP associated neuropathy (irreversible)

❒ Radical prostatectomy ❒ Other (specify) _____

❒ Synagis (Check applicable age, condition and risk factors)

Current weight _____lbs.

❒ Gestational age ≤ 28 wks & infant is < 12 months ❒ Child is < 24 months old with Chronic Lung Disease*

❒ Gestational age 29-32 wks & infant is < 6 months ❒ Child is < 24 months old with Congenital Heart Disease*

❒ Gestational age 33-35 wks & infant < 6 months with AAP risk factors*

AND

❒ Currently outpatient with no inpatient stay in the last 2 weeks.

*Document AAP risk factor(s) and/or other required medical justification in the Drug/Clinical Information Section of this form.

❒ Specialized Nutritionals

Height _____ inches Current weight _____lbs.

❒ If < 21 years of age, record supports that > 50% of need is met by specialized nutrition

❒ If ≥ 21 years of age, record supports 100% of need is met by specialized nutrition

Method of administration _____ Duration _____ # of refills _____

FOR HID USE ONLY

❒ Approve request ❒ Deny request ❒ Modify request ❒ Medicaid eligibility verified

Comments _____

_____

_____ _____

Reviewer's Signature Response Date/Hour

Alabama Medicaid
Preferred Drug and Prior Authorization Program

Effective October 1, 2003, as a result of legislation passed in June 2003, the Alabama Medicaid Agency will use a mandatory Preferred Drug List. Brand preferred drugs, generics and over-the-counter drugs covered by Medicaid will be available without prior approval. If, however, a non-preferred drug is ordered the practitioner will need to get prior authorization. If approval is given to dispense the non-preferred drug, an authorization number will be given. Antipsychotic and HIV/AIDS drugs are exempted from the new requirements.

The following entries contain detailed instructions on completing the Medicaid Prior Authorization Form, as well as answers to frequently asked questions about the Medicaid Pharmacy Program.

Section 1: General Information
Section 2: Patient Information
Section 3: Prescriber Information
Section 4: Pharmacist Information
Section 5: Drug/Clinical Information
Section 6: Drug Specific Information
Section 7: Exempted Medications
Section 8: FAQs

Both pages of the Prior Authorization form need to be completed and faxed for requested drug or nutritional. Please complete a separate form for each drug/nutritional requested.

Section One: General Information

- **Preferred Drugs**

  Effective October 1, 2003 the following classes of drugs will be on the mandatory preferred drug list:

  - **Narcotics**
  - **Antidepressants**
  - **Platelet Aggregation Inhibitors**

  Other drug classes will be added as they are reviewed and approved.

- **Verbal Requests**

  PA requests for the drugs that meet the previous drug usage requirements for approval will be accepted verbally. Verbal PA requests may be initiated by Pharmacists, Physicians or their authorized representative. Any drug requiring additional information or medical justification must be submitted on the required PA form. Drugs that may be requested verbally are listed below:

  - **NSAIDs**
  - **Antihistamines**
  - **H2 Antagonists**
  - **PPI**
  - **Antidepressants**
  - **Narcotic Analgesics**
  - **Platelet Aggregation Inhibitors**

- **PA Approval Timeframes**

  NSAID - Approval may be given for up to 12 months.
  Antihistamine - Approval may be given for up to 12 months.
  H2 Antagonist - Approval may be given for up to 12 months for maintenance.
  PPI - Approval may be given for up to 12 months for maintenance.
  Sustained Release Oral Opioid Agonist - Approval may be given for up to 12 months with a qualifying diagnosis code.
  Tumor Necrosing Factor - Approval may be given for up to 12 months.
  Xenical - Approval may be given for up to 3 months with initial request, and up to 6 months for each subsequent request to a total approval period not to exceed 2 years for the recipient.
  Erectile Dysfunction Drugs - Approval may be given for up to 30 days for initial request (not to exceed 4 tablets in this 30 day period), with up to 3 months allowed for renewal requests.
  Synagis - Approval may be given for up to 6 months or through the end of RSV season (March 31), which ever comes first.
  Specialized Nutritionals - Approval may be given for up to 12 months.
  Antidepressants - Approval may be given for up to 3 months with initial request, up to 6 months with renewal requests
  Narcotic Analgesic - Approval may be given for up to 12 months with initial and renewal requests.
  Platelet Aggregation Inhibitors – Approval may be given for up to 6 months with initial request and up to 12 months with renewal requests.

Section Two: Patient Information

- Record the patient's name as it appears on their Medicaid card, and their Medicaid number.
- Record patient's date of birth.
- Fill in the patient's phone number with area code.

- Indicate whether the patient is a nursing home resident.

Section Three: Prescriber Information

- Record the prescribing practitioner's name and license number, along with address, phone number and fax number with area codes.
- The prescriber should sign and date in this section on the prescribing practitioner signature line. By signing in the space indicated the practitioner verifies that the request complies with Medicaid's guidelines and that he/she will be supervising the patient during treatment with the requested product. The practitioner further certifies that documentation is available in the patient record to justify the requested treatment.

Section Four: Dispensing Pharmacy Information

- Enter the pharmacy name and provider number.
- Enter phone number and fax number with area code.

Section Five: Drug/Clinical Information

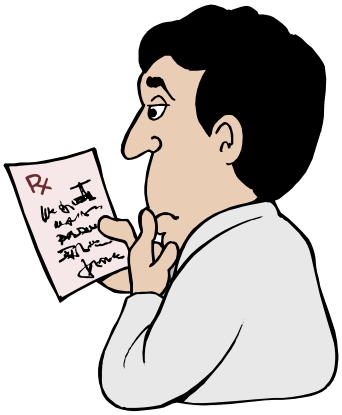
- **This information is required for all requests.**
- Record the name of the drug and the strength requested.
- Enter the NDC number, or J Code for injectables, along with the quantity of the drug requested per month and number of refills requested.

- Record diagnosis(es) that justifies the drug requested. **The ICD-9 code is required for the following drugs/drug classes: Growth Hormones, SROAs, TNF Blockers, Synagis and Specialized Nutritionals.**
- Indicate whether this is a first request or renewal request.
- Explain the reason this drug is required, and attach any additional medical justification necessary. Medical justification is documentation to support the physician's choice of the requested course of treatment. Documentation from the patient's record (history and physical, tests, past or current medication/treatments, patient's response to treatment , etc) illustrates and supports the physician's request for the drug specified. For example, if a recommended therapy trial is contraindicated by the patient's condition or a history of allergy to a first-line drug, and the physician wants to order a preferred drug, documentation from the patient's record would support that decision.

Section Six: Drug Specific Information

NSAID/Antihistamine/H2 Antagonist/PPI/Antidepressants/Narcotic Analgesics/Platelet Aggregation Inhibitors

- Prior authorization requires that two (2) prescription generic/OTC/brand name drugs have been utilized unsuccessfully relative to efficacy and/or safety within six (6) months prior to requesting the PA. The PA request must indicate that two (2) generic, OTC or other brand drugs have been utilized for a period of at least thirty (30) days each, **unless** there is an adverse/allergic response or contraindication. If the prescribing practitioner feels there is a medical reason for which the patient should not be on a generic/OTC/brand drug or drug trial, medical justification may be submitted in lieu of previous drug therapy.
- Check the applicable drug classification requested. For H2 antagonists and PPIs note whether this request is for **acute** or **maintenance therapy.**
- List previous drugs that were used unsuccessfully (generic, brand, and over the counter drugs) and the reason that each drug was discontinued. **If there were no failed trials with other drugs, additional medical justification must be provided to justify the request.**
- For **antihistamines**, if the physician feels there is a medical reason the patient should not be on a sedating antihistamine, medical justification may be submitted for review.
- If the drug requested is a **COX II,** please submit medical justification, which should include the relevant diagnosis, any additional diagnoses, and any history preventing the use of other NSAIDs.



- If the drug is an **H2 Antagonist,** approval may be given without failed drug trials **if** a relevant diagnosis and documentation of testing with date and results are provided.
- If the drug requested is a **PPI** and there were no failed trials with other therapies and lifestyle modifications, medical justification must be submitted documenting testing with date and results. No prior history of drug use is needed to approve request in the presence of relevant diagnosis, documentation of lifestyle modifications and appropriate testing. Lifestyle modifications include elevation of the head of the bed (on 6-inch blocks or foam wedge), avoiding lying down within 3 hours after meals, avoiding acidic foods (tomato products, citrus fruits, spicy foods, coffee) and agents that relax the lower esophageal sphincter or delay gastric emptying time (fatty foods, peppermint, chocolate, alcohol, smoking), weight loss, avoidance of bending after meals, and reduction of meal size. Additional medical justification for consideration for approval outside criteria may be attached, including medical justification for the absence of lifestyle modifications in nursing home patients. For PPIs, medical justification need is diagnosis driven and outlined as follows:

GERD

Medical justification documentation **must** indicate lifestyle modifications implemented and failure of OTC/generic/brand H2 antagonists prescribed for at least 8 weeks with persistence of symptoms. Testing (H pylori testing, UGI/barium swallow, endoscopy) is not required for acute therapy with moderate to severe symptoms, defined as $\geq$ 2 episodes/week of nocturnal heartburn, and $\geq$ 3 episodes/week of daytime heartburn or indigestion, with no resolution or worsening of symptoms. Approval may be given for up to 4 weeks of acute therapy. If moderate to severe symptoms persist and there is documentation in the medical record of compliance with lifestyle modifications an additional 8 weeks of treatment may be approved

without testing. If symptoms persist, documentation of appropriate testing with results is required for approval of additional maintenance therapy.

H pylori

If the patient has tested positive for H pylori, approval may be given for up to a 4 week course of treatment. No prior history of drug use is needed to approve request in the presence of relevant diagnosis and appropriate testing.

Peptic Ulcer Disease

If the patient has been diagnosed with an active duodenal ulcer by endoscopy or UGI within the past 12 months, up to 4 weeks of acute therapy may be approved. If the patient has been diagnosed with an active gastric ulcer by endoscopy or UGI, up to 8 weeks of acute therapy may be approved. If severe symptoms persist **and** there is documentation of lifestyle modifications, an additional 8 weeks of treatment may be approved for duodenal ulcers and for gastric ulcers.

Hypersecretory Conditions

If the patient is diagnosed with Barrett's Esophagitis, Zollinger-Ellison, or other hypersecretory disorders, which have been confirmed by testing, then approval of up to 12 months of acute treatment may be issued, with continued maintenance therapy approved in 12 month increments. Renewal requests do not require retesting but do need documentation of persistence of symptoms.

- If the drug requested is an **Antidepressant,** medical justification may be submitted in lieu of prior usage requirements. Acceptable medical justification may consist of the indication of "stable therapy" providing the original start date of the requested medication is provided with an indication of why the specific brand requested is medically necessary, documentation of allergies or contraindications to all preferred agents or significant past history of depression containing information related to the specific episode(s) i.e. past hospitalization for depression, suicidal attempt, or counseling with concomitant depression.

- If the drug requested is a **Narcotic Analgesic,** medical justification may be submitted in lieu of prior usage requirements and may consist of diagnosis and ICD-9 codes, documentation of therapeutic pain management failure with NSAIDs, APAP, or ASA and must consist of a complete pain evaluation in the medical record. Type of pain (acute versus chronic) and pain intensity (mild, moderate or severe) must be indicated in the Drug/Clinical Information section, Medical Justification.

- If the drug requested is a **Platelet Aggregation Inhibitor,** medical justification may be submitted in lieu of prior usage requirements. Acceptable medical justification may consist of clinical diagnoses indicating 1st line treatment by certain branded products in lieu of ASA, documentation of contraindication or intolerance to the use of ASA, ticlopidine and dipyridamole. Clinical literature reviewed supports the use of certain branded products for specific indications; Plavix® (Clopidogrel) and Aggrenox® (ASA/DP-ER) are indicated for ***TIA Management if TIA occurs while on ASA***. Plavix® (Clopidogrel) is indicated as an

adjunct to ASA in ***stent placement (percutaneous coronary intervention)*** or in patients with ***unstable angina***. Plavix® (Clopidogrel) may be better as 1st line treatment for ***chronic extremity arterial insufficiency***. In addition, ACCP guidelines recommend Pletal® (cilostazol) for patients experiencing ***disabling claudication when revascularization cannot be performed***, not recommended for routine use in intermittent claudication.

Sustained Release Oral Opioid Agonist

- **Diagnosis and ICD-9 code are required for this drug class (see Section Five: Drug/Clinical Information).**
- Approval may be given for the treatment of intractable, chronic pain with oral SR opioid agonists (OxyContin®, Kadian®, Oramorph SR®, MS Contin®, Avinza™). These medications are narcotic analgesics and Schedule II controlled substances. They are not intended for use with acute pain, as a PRN analgesic or for short-term pain management (≤ 10 days). The patient must have had failed 30 day trials with alternative pain management therapies and non-opioid adjuvant drugs to replace or enhance opioid analgesia, unless the primary diagnosis is an approved cancer diagnosis. Submission of a plan of action addressing continued medical monitoring, titration and a written signed contract for therapy is required for patients with a history of substance abuse or addiction, unless the patient is a nursing home resident. For nursing home residents with a history of substance abuse or addiction, medical justification may be submitted in lieu of a plan of action, alternate pain management choices and adjuvant therapy. For patients ≥ 65 years of age, medical justification may be provided in lieu of non-opioid adjuvant drugs.
- Indicate how long patient will require treatment with Sustained Release Opioid Agonists (SROAs).
- You must indicate whether drug is intended for PRN use. **SROAs are not for short-term pain management (≤ 10 days) or for PRN use.**
- Indicate the type of pain and severity. **SROAs are not intended for use with acute pain.**
- Indicate prior and/or current analgesic drugs used and alternative management choices. **The patient must have had failed 30 day trials with alternative pain management therapies and non-opioid adjuvant drugs to replace or enhance analgesia, unless the patient has an approved cancer diagnosis.**
- Indicate whether the patient has a history of substance abuse or addiction. **If the answer is yes, a treatment plan (a plan of action addressing continuing medical monitoring, titration, and a written signed contract for therapy) must be attached to the request, unless the patient is a nursing home resident.**

Tumor Necrosing Factor (TNF) Blockers

- **Diagnosis and ICD-9 code are required for this drug class (see Section Five: Drug/Clinical Information).**
- Check the applicable drug.
  - **A. Remicade® (Infliximab)**
    Rheumatoid Arthritis
    For prior authorization the patient must have a diagnosis of rheumatoid arthritis [diagnosis of rheumatoid arthritis or other rheumatoid arthritis

with visceral or systemic involvement, or polyarticular juvenile rheumatoid arthritis] that has been confirmed by a board certified rheumatologist. The patient must also have a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), at least one of which is Methotrexate, unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathriprine, oral gold, intra-muscular gold. The patient will need to continue on Methotrexate in conjunction with Remicade therapy, unless there is a contraindication to its use. Any contraindications or intolerance to Methotrexate use will need to be identified with appropriate supportive documentation included.

Crohn's Disease

For prior authorization the patient must have a diagnosis of moderately to severely active Crohn's disease [diagnosis of regional enteritis (Crohn's disease or granulomatous enteritis) of the small intestine, large intestine, small intestine with large intestine, and/or unspecified site, anal fistula and/or fistula of the intestine, excluding rectum and anus] that has been confirmed by a board certified gastroenterologist. To be approved, the patient must have had an inadequate response (persistence of significant and/or progressive weight loss, fevers, abdominal pain or tenderness, intermittent nausea or vomiting and/or significant anemia or increase or lack of reduction in the number of draining enterocutaneous fistulae in patients with fistulizing Crohn's disease) to one or more conventional therapies, which include aminosalicylates, corticosteroids, azathioprine/6-mercaptopurine, metronidazole, ciprofloxin, cyclosporin.

B. <u>Enbrel® (Etanercept)</u>

For prior authorization the patient must have a diagnosis of rheumatoid arthritis, polyarticular juvenile rheumatoid arthritis or psoriatic arthritis. Submitted documentation must include evidence that physical therapy, non-steroidal anti-inflammatory drugs and local/oral steroids were tried without success, and that the course of treatment with Enbrel® is recommended by a board certified rheumatologist or dermatologist. The patient must also have a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

C. <u>Kineret® (Anakinra)</u>

For prior authorization the patient must have a diagnosis of moderately to severely active rheumatoid arthritis. Submitted documentation must include a diagnosis of rheumatoid arthritis, confirmation of drug therapy by a board certified rheumatologist, and a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

D. <u>Humira™ (Adalimumab)</u>

For prior authorization the patient must have a diagnosis of moderately to severely active rheumatoid arthritis. Submitted documentation must include confirmation by a board

certified rheumatologist. The patient must also have a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

- Indicate whether diagnosis has been approved by a board certified rheumatologist if diagnosis is rheumatoid arthritis
- Indicate prior and/or current DMARD therapy (see requirements for each drug above)
- Crohn's disease therapy must be approved by a board certified gastroenterologist
- Patients on Remicade® for rheumatoid arthritis must also be on Methotrexate unless contraindicated. If answer is no, contraindication must be explained.

Xenical®

- To receive prior authorization for Xenical®, the patient must be 18 years of age or older and have at least one of the following primary medical diagnoses: Diabetes Mellitus, Hypertension, or Hyperlipidemia.
- For initial requests the patient's height (in inches), weight (in pounds) and BMI are required.
- Renewal requests require the patient's previous and current weights (in pounds). **Continued weight loss must be documented for renewals.**
- There must be documentation in the patient record to support failure with prior physician supervised exercise/diet regimen(s) of at least 6 months duration. Documentation must also show that adjuvant therapy is planned.
- Dosage requested must not exceed 120 mg TID.

Erectile Dysfunction Drugs

- For prior authorization, documentation of erectile dysfunction must be confirmed by history and by physical examination. Documentation must also show failed trial with at least one drug or device within the past 12 months. Previous drug or device therapy may include Testosterone and Testosterone gel, Prostaglandin (PEG1) Injections (Caverject®, BIMIX, Edex®) or intraurethral pellets/suppositories (MUSE), Yohimbine®, Phentolamine (Regitine), and vacuum devices. Drugs for erectile dysfunction should not be prescribed for those with active or recent history of a sexually transmitted disease or for those under 18 years of age. Approval may be given for no more than four (4) tablets of any strength for 30 days.

- Fill in patient's gender. These drugs are approved **only** for male patients.
- Indicate whether the patient has an active or recent history of a sexually transmitted disease.
- The nature or cause of dysfunction must be indicated, confirmed by documented history and physical exam.

Synagis®

- **Diagnosis and ICD-9 code are required for this drug class (see Section Five: Drug/Clinical Information).** See Synagis Worksheet for appropriate diagnosis codes.
- Synagis® has been approved by Alabama Medicaid for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk for RSV disease. The patient must meet the gestational age, age at request requirements, and must be an outpatient with no in-patient stay for at least two weeks prior to the date of the medication request. Infants less than six (6) months old with gestational age of 33-35 weeks may qualify with 2 or more of the AAP risk factors (child care attendance, school-age siblings, congenital abnormalities, severe neuromuscular disease, and low birth weight {< 2500 grams}).
- Additional medical justification for high-risk toddlers less than twenty four (24) months of age may be given for hemodynamically significant CHD (Congenital Heart Disease) or CLD (Chronic Lung Disease) with documentation provided as defined. For CLD documentation must support continuation of CLD treatment through RSV season consisting of supplemental O2, bronchodilators, oral steroids, inhaled steroids, or diuretics.
- Patients who have received prior authorization should receive monthly doses throughout the RSV season as defined by the Alabama Medicaid Agency. RSV prophylaxis approval will terminate at the end of RSV season.
- Current weight is required
- In addition to the above the patient must also be an out patient with no inpatient stay within the past 2 weeks.
- Check appropriate category for age, condition and risk factors.
- Approval authorizes only one (1) dose (based on patient weight) every thirty days up to a six (6) dose maximum or through the end of RSV season (March). **No dose may be given after March 31, and requests for more than one dose in a thirty-day period cannot be approved.** RSV prophylaxis will end at the end of RSV season.
- **Medical documentation acceptable for Synagis® prior authorization must include all medications, frequency of medication dosing, and diagnosis(es) with indications of severity of illness. A periodic review of medical records will be conducted by the Alabama Medicaid Agency or designees.**

Specialized Nutritional

- **Diagnosis and ICD-9 code are required for this classification (see Section Five: Drug/Clinical Information).**
- Patients who, because of illness or trauma, cannot be sustained through oral feedings and must rely on enteral nutrition therapy may qualify for coverage under Medicaid. Enteral nutrition may be administered by nasogastric, jejunostomy, or gastrostomy tubes.
- Specialized nutrition is covered for Medicaid eligible EPSDT recipients under 21 years of age with nutritional disorders. They do not have to be tube fed, but the specialized feeding

must constitute more than 50% of their nutritional needs. A qualifying diagnosis is required.

- Recipients age 21 and over who must rely on enteral feedings as their only source of nutrition may qualify for Medicaid coverage if they have a qualifying diagnosis and meet disease specific criteria.
- Current height and weight are required.
- Select appropriate age category
- Indicate how specialized nutritional is administered, along with the duration and number of refills.
- Prior authorization is for the nutritional product only and does not include any equipment or supplies necessary to administer the nutrients. Supplies and equipment used in conjunction with nutritional therapy may be covered in the Medical Supplies, Appliances and Durable Medical Equipment Program. For more information on supplies and equipment, see Chapter 14 of the Medicaid Provider Manual or contact Medicaid Provider/Recipient Services at 1-334-293-5504.

Section Seven: Exempted Drugs

Currently only antipsychotics and HIV/AIDS drugs are exempted from the mandatory preferred drug list and new prior authorization requirements.

Section Eight: Frequently Asked Questions

1. What is difference between the new PDL and the old PDL?

- Medicaid is implementing a **mandatory** Preferred Drug List. The previous PDL was voluntary and for educational purposed only.
- Preferred drugs are products that have been evaluated as to safety, efficacy and therapeutic value. They are, within their classes or categories, therapeutically equivalent and effective.

2. How will this affect my practice?

- Brand drugs within the scope of the PDL but not on the preferred drug list the will require prior authorization.
- Prescriptions that are written for brand preferred drugs, generic and over-the-counter drugs will not require prior authorization.

3. What drugs will be on the Preferred Drug List?

- Generic and over-the-counter drugs covered by Medicaid will be preferred agents. Additionally, certain brand name drugs will be preferred agents.
- HIV/AIDS drugs and antipsychotics are excluded from the list so prior authorization is NOT necessary for these categories.

4. Who determines which drugs are on the Preferred Drug List?

- Medicaid will utilize a Pharmacy and Therapeutics Committee (P&T) Committee to develop a Preferred Drug List based on clinical efficacy, safety, and patient care factors.

- The P&T Committee is comprised of at least 5 practicing physicians nominated by the Medical Association of the State of Alabama and 3 clinical pharmacists nominated by the Alabama Pharmacy Association.
- Members of the P&T Committee represent various fields of specialty including psychiatry, internal medicine, pediatrics, long-term care, and independent pharmacy.

5. Will this keep my patients from getting the drugs they need?

- No, reasonable responses to prior authorization requests are available and an automatic approval mechanism is in place for a 72 hour emergency supply.
- The plan will be driven by patients' medical needs, provide for prompt decision making, include a fair appeals process for patients and providers and be minimally burdensome to prescribers.
- Patients will not be placed in jeopardy because the Preferred Drug List will be based on clinical effectiveness above all other considerations.
- Prior authorization of medications that are non-preferred drugs does not prevent patients from receiving the medication. A physician may request a prior approval for non-preferred drugs.

6. When will the changes be implemented?

- The list will be implemented in phases.
- The first set of drugs will begin on October 1, 2003 and be phased in over a period of approximately 6 months.

7. Are drug costs ever a factor in determining what goes on the preferred list?

- Clinical issues such as efficacy and side effects are primary considerations in determining which drugs are preferred. The P & T Committee does not have cost information when they review clinical information and make their recommendation. Cost information may be considered by Medicaid if, and only if, the P & T Committee determines drugs within a class are equally safe and effective.

8. Are original prescriptions and signatures required for all drugs?

- Medicaid requires original, signed prescriptions for Schedule II drugs and Brand Medically Necessary drugs.
- Schedule III, IV, and V drugs may be called in, as allowed by state pharmacy regulation.

9. Can a call-in prescription be accepted for a MAC drug when brand necessary certification is required?

- No. The MAC price may only be waived when a pharmacy has a prescription with "Brand Medically Necessary" written in the prescribing physician's own handwriting. Therefore, having a written prescription is necessary. For example, because Zantac is a MAC drug and requires brand medically necessary certification on the prescription, a telephone prescription would not be acceptable in order to receive brand reimbursement.

10. Can I make a therapeutic or strength substitution without calling the prescribing physician?

- No. Alabama State law requires the pharmacist to have the approval of the prescribing physician before dispensing anything other than what has been indicated on the prescription.
- If the physician has indicated product selection is allowed, the pharmacist may dispense generic substitution without subsequent contact with the physician.

11. What is the appropriate action when a physician writes a prescription that exceeds the Medicaid monthly dosing units?

- When a prescription is denied for excessive quantity or monthly limit exceeded, claims will deny. In order to receive an override, providers (either the pharmacy or physician) should contact the HID help desk (1-800-748-0130) for consideration of an override.

12. How long is a prescription valid?

- In accordance with state law, controlled substance prescriptions are valid for up to six (6) months from the original issue date.
- Non-controlled prescriptions are reimbursable by Medicaid for up to twelve (12) months from the date of the original dispensing date.

13. Can I receive authorization for additional refills from the prescribing practitioner after twelve (12) months have expired?

- No. A new prescription should be obtained after twelve (12) months from the date of the original dispensing date.
- Medicaid will make payment for up to 5 refills on an original prescription. The pharmacist should not request additional refills from the physician.

14. Why is it important that I bill the exact NDC number dispensed if the product is a generic?

- According to Jerry Moore, State Board of Pharmacy, pharmacies dispensing controlled substances and submitting claims with different NDC numbers will have problems with the Drug Enforcement Agency (DEA). Additionally, Medicaid provider contracts require that claims be submitted accurately. Under federal law, manufacturers rebate Medicaid for use of their drugs. When an NDC is submitted on a claim that is not the actual NDC dispensed, Medicaid may incorrectly invoice the manufacturer for the rebate. Rebate dollars provide a significant source of money to offset pharmacy benefit costs. Therefore, NDC numbers reported on pharmacy claims should be the exact NDC number dispensed to the patient.

15. Can referrals be made to Medicaid when a provider believes a recipient is defrauding the program?

- Yes. Information about possible illegal drug-related activity, abuse, misuse or fraud by Medicaid recipients can be referred to 1-800-362-1504.

- All complaints are researched. If evidence is found to support recipient abuse or fraud, recipients can be locked in to one physician and one pharmacy, removed from the Medicaid program, or referred to the District Attorney.

16. Does Medicaid make payment for benefits when a patient is in a state or county correctional facility?

- After a recipient has been convicted and is incarcerated, the recipient may no longer receive Medicaid benefits. It is the responsibility of the correctional facility to provide medical care.
- Youth in the custody of the Department of Youth Services (indicated by County Code 69) may be eligible for Medicaid coverage. Providers should continue to verify eligibility prior to dispensing medications.
- For additional information regarding incarcerated recipients and Medicaid coverage, call 1-800-362-1504.

17. If a provider receives multiple dispensing fees for the same patient, same drug and strength within the same month, will the additional dispensing fees be recouped?

- Medicaid auditors look specifically for providers who split 30-day prescriptions into shorter time periods and amounts. **Intentionally splitting prescriptions to receive multiple dispensing fees is fraud, monies paid will be recouped, and appropriate referrals may be made to the Attorney General's offiice.**
- Multiple dispensing fees within the same month for the same patient and same drug are acceptable if the provider has documentation supporting the need for multiple dispensings. **Example:** A provider writes a 30 day prescription for a medication and there is only 7 days of medication in the pharmacy. The patient is given the 7 day supply and a dispensing fee is charged. When the patient returns for the rest of the prescription, the pharmacist can not charge for a second dispensing fee.

18. If a provider is audited and can not produce documentation while Medicaid auditors are in the store, is there a period of time allowed to provide the documentation before recoupments are initiated?

- If an auditor requests documentation that is not present in the provider's facility, the provider should indicate to the auditor where the documentation is and when it can be provided for review.
- If additional information is needed by the state as a result of discrepancies identified in an audit, the provider should submit the requested information within 30 days of the request. Failure to submit documentation within 30 days may result in recoupment and additional action as necessary.